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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,412	12/21/2000	Wouter E. Roorda	50623.26	3752

7590 09/26/2007

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EXAMINER	
GANESAN, SUBA	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
09/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/748,412	ROORDA, WOUTER E.	
	Examiner	Art Unit	
	Suba Ganesan	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,10,12,18-20 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,10,12,18-20,25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/18/2007 have been fully considered but they are not persuasive. Wolff et al. (WO 91/12779) discloses loading different drugs with different elution properties on separate layers of polymer (fig. 3B, pg. 15 lines 11-21). This clearly indicates that the device of Wolff is capable of providing an initial release of a first drug and a delayed release of a second drug.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2-3, 18-19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779).

Wolff et al. discloses a stent and method of inhibiting restenosis (pg. 1 lines 1-5, fig. 3B) using a polymeric layer (pg. 12 line 15- pg. 15 line 21) with a component for reducing the formation of thrombi (for example heparin, pg. 8 lines 33-37) and a second layer for reducing or preventing infiltration of macrophages into the thrombi (for example aspirin pg. 8 lines 13-23). Wolff further discloses loading different drugs in separate layers of the implant, with an initial release of a first drug and a delayed release of a second drug (fig. 3b and pg. 15 lines 11-21). However, Wolff is silent as to the order of

the drugs loaded on separate layers of the device. It would have been obvious to one of ordinary skill in the art to provide an initial release of a component for reducing the formation of thrombi prior to an initial release of component for reducing the infiltration of macrophages, since both of these components are disclosed in the Wolff publication and a finite number of combinations of drug layering exists. One of ordinary skill in the art would find it obvious to try loading different available therapeutic agents into different layers as taught by Wolff to create implants tailored to specific patients or medical conditions.

It would have further been obvious to one of ordinary skill in the art at the time of the invention to provide an initial release of a substance for the treatment of thrombus formation prior to an initial release of an anti-inflammatory substance, since both of these components are disclosed in the Wolff publication and a finite number of combinations of drug layering exists. One of ordinary skill in the art would find it obvious to try loading different available therapeutic agents into different layers as taught by Wolff to create implants tailored to specific patients or medical conditions.

3. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Iguchi et al. (U.S. Pat. No. 5756553).

Wolff is explained supra. However Wolff does not disclose the polymer as ethylene vinyl alcohol. Iguchi et al teaches coatings for stents comprising ethylene vinyl alcohol blended with a drug (e.g. col. 3, lines 29-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the

teaching of coatings for stents comprising ethylene vinyl alcohol blended with a drug, as taught by Iguchi et al, to the coated stents as per Wolff et al, because ethylene vinyl alcohol has proven to have extremely high stability and safety, and is stably supplied and inexpensive (Iguchi et al col. 3, lines 12-19).

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Berg et al. (U.S. Pat. No. 5464650).

Wolff et al is explained supra. In addition, Wolff discloses loading different drugs in separate layers of the implant, with an initial release of a first drug and a delayed release of a second drug (fig. 3b and pg. 15 lines 11-21). However, Wolff is silent as to the order of the drugs loaded on separate layers of the device. It would have been obvious to one of ordinary skill in the art to provide an initial release of an anti-thrombogenic substance prior to the release of the ant-inflammatory substance since one of ordinary skill would find it obvious to try loading different available therapeutic agents into different layers as taught by Wolff to create implants tailored to specific patients or medical conditions.

However, Wolff does not disclose a layer comprising betamethasone. Berg teaches the use of betamethasone as a stent coating (eg. Col. 2 lines 30-67). Therefore it would have been obvious to one of ordinary skill in the art to modify the coating of Wolff to include a coating of betamethasone as taught by Berg for the purpose of utilizing the anti-inflammatory properties of betamethasone.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Berg et al. (U.S. Pat. No. 5464650), as applied above, further in view of Iguchi et al. (U.S. Pat. No. 5756553).

Wolff in view of Berg et al. is explained supra. However Wolff does not disclose the polymer as ethylene vinyl alcohol. Iguchi et al teaches coatings for stents comprising ethylene vinyl alcohol blended with a drug (e.g. col. 3, lines 29-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of coatings for stents comprising ethylene vinyl alcohol blended with a drug, as taught by Iguchi et al, to the coated stents as per Wolff et al, because ethylene vinyl alcohol has proven to have extremely high stability and safety, and is stably supplied and inexpensive (Iguchi et al col. 3, lines 12-19).

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Lee (U.S. Pat. No. 5123917).

Wolff is explained supra. However, Wolff does not disclose a layer made of PTFE. Lee teaches the use of a stent comprising a layer of PTFE impregnated with a corticosteroid (col. 4 line 65-col. 5 line 10). Therefore it would have been obvious to one of ordinary skill in the art to combine the PTFE layer impregnated with a corticosteroid, as taught by Lee, with the specific therapeutic agents of Wolff et al for the purpose of creating an inert polymeric layer that delivers a therapeutic agent to minimize tissue proliferation.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 9/18/2007

Brian E Pellegrino

BRIAN E. PELLEGRINO
PRIMARY EXAMINER